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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,783	05/28/2002	Lynn Repsis Fraser	78104.037	6101

7590 05/21/2004

Intellectual Property Department
Dewitt Ross & Stevens
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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,783	FRASER, LYNN REPSIS	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *34-43,47 and 51-88* is/are pending in the application.

4a) Of the above claim(s) *58-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *34-43,47,51-57 and 88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 34-43, 47 and 51-57 as amended and new claim 88 [filed 2/23/2004] are pending and under examination.

Claims 58-87 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Claims 1-33, 44-46 and 48-50 were canceled by applicant.

Response to Arguments

Applicant's arguments filed 2/23/2004 have been fully considered but they are not persuasive for the reasons below.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejection under 35 U.S.C. 102(b) as being anticipated by US 5,698,549 has been withdrawn because the cited patent does not disclose a composition that contains calcitonin as required by amended claims.

Claims 40 as amend and new claim 88 remains/is rejected under 35 U.S.C. 102(b) as being anticipated by Schmid et al. as explained in the prior office action and for the reasons below.

Claims are directed to a composition suitable for contacting mammalian sperm contacting wherein the composition consists essentially of a combination of two ingredients that are 1) calcitonin and 2) angiotensin II. Some claims are further drawn to incorporation of a pharmaceutical carrier into the composition.

Schmid et al. disclose a pharmaceutical composition wherein the composition contains a combination of two active agents that are 1) calcitonin and 2) angiotensin II, for example: see the injection composition at figure 6. The disclosed composition is an injection for mammalian animals and, thus, it comprises a pharmaceutical carrier suitable for mammalians cells including sperm cells. The disclosed composition is identical to the presently claimed composition because it consists of identical components as required by the presently claimed invention. Thus, the effects that would be produced by the composition of the cited reference under the same conditions as intended for the instant invention are presumed to be inherently identical to the properties/effects as intended for the presently claimed composition. Thus, the cited reference is considered to anticipate the claimed invention.

Applicant's argument that the cited composition does not contain calcitonin and angiotensin II together in one composition (response page 17) is not found true. Figure 6 clearly demonstrates both agents in one composition. The paragraph that describes this experiment (page R1649 col. 2, line 7) clearly discloses one injection composition with calcitonin and ANG II together. There is nothing "ambigious" as argued about this specific combination of two agents that are identical to agents as required for the claimed invention. The fact that the composition is used for a different purpose does not create material differences between the cited composition and the presently claimed composition. If there are no material differences between two

compositions, there would not be any differences in a functional manner that appears to be argued.

Claims 34, 35 and 40 as amended and new claim 88 remain/is rejected under 35 U.S.C. 102(b) as being anticipated by US 6,153,582 as explained in the prior office action and for the reasons below.

Claims are directed to a composition comprising a combination of two agents that are 1) calcitonin and 2) a modulator of adenosine receptor activity that is adenosine. Some claims are further drawn to incorporation of a suitable pharmaceutical carrier into the composition.

US 6,153,582 [B] discloses an animal cell medium composition (col. 3-4) wherein the composition has a combination of two agents that are 1) hormonal supplement or calcitonin (col. 4, line 35) and 2) adenosine (col. 4, line 14). The disclosed composition is intended for culturing and/or maintaining animal cells and, thus, it comprises suitable pharmaceutical carriers including carriers for topical applications related to animal cells either corneal cells or sperm cells within the meaning of the instant claims. The disclosed composition is identical to the presently claimed composition because it has both components as required by the presently claimed invention. Thus, the effects that would be produced by the composition of the cited patent under the same conditions as intended for the instant invention are presumed to be inherently identical to the properties/effects as intended for the presently claimed composition. Thus, the cited patent is considered to anticipate the claimed invention.

As related to the composition of the cited patent applicant argues that it contains awesome number of other ingredients and that some of the other ingredients could have negative

effects on sperm cells. However, the prior art composition would reasonably be expected to have the same basic and novel characteristic of the claimed composition because it said to contain two components that are required for the claimed composition. When an applicant contends that additional materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Applicant argues the negative effect of other component but does not point out and does not identify them. The cited composition is animal cell medium and, thus, all disclosed components are reasonably expected to be suitable for animal cells including sperm cells. Moreover, it contains 2 claimed components as intended by applicant for sperm capacitation. Until a satisfactory showing is made, the term "consisting essentially of" is considered to be the equivalent of "comprising". See MPEP

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 34-43, 47 and 51-57 as amended and new claim 88 remain/is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/32725, Suzuki et al. and Fraser as explained in the prior office action and for the reasons below.

Claims are directed to a medication composition for increasing capacitation of mammalian sperm or treating infertility in humans wherein the composition comprises a combination of two agents or more agents selected from calcitonin, angiotensin II and a

modulator of adenosine receptor activity. Some claims are further drawn to the use of a modulator of adenosine receptor activity selected from fertilization promoting peptide (FPP), adenosine or combination of FPP and adenosine in the composition. Some claims are further drawn to incorporation of a suitable pharmaceutical carrier into the composition. Some claims are further drawn to the use of calcitonin derived from salmon, porcine or human sources. Some claims are further drawn to the use of particular concentrations of agents in the composition.

The cited references are relied upon as explained in the prior office action and repeated herein.

WO 95/32725 discloses a composition for increasing function or capacitation of mammalian sperm or treating infertility in humans wherein the composition comprises agent such as angiotensin II (abstract). It also teaches the agent concentrations and suitable carriers for the medication composition for increasing capacitation of mammalian sperm or treating infertility in humans (examples 1-5). But it lacks disclosure related to the use of calcitonin, FPP and/or adenosine in the composition.

However, the reference by Fraser discloses a medication composition for increasing capacitation of mammalian sperm or treating infertility in humans wherein the composition comprises agents such as fertilization promoting peptide (FPP) or adenosine or combination of FPP and adenosine in the composition (abstract). The reference also teaches the agent concentrations (page 242, col. 2). But it lacks the disclosure related to angiotensin II and calcitonin.

The reference by Suzuki et al. teaches calcitonin as agent effective for increasing capacitation of mammalian sperm and, thus, for treating infertility in mammalians.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine three agents that are 1) angiotensin II, 2) calcitonin and 3) FPP and/or adenosine in one composition with a reasonable expectation of success for increasing capacitation of mammalian sperm or treating infertility in humans because each agent has been known and/or used in compositions for increasing capacitation of mammalian sperm or treating infertility in mammalians including humans as adequately demonstrated by the cited prior art references. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinter, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. It is considered to be within the purview of the ordinary skill practitioner to adjust agent concentrations with regard to a particular application and/or with regard to a various source of calcitonin agent including salmon, porcine and/or human sources of derivatization. It is considered to be within the purview of the ordinary skill practitioner to select the pharmaceutical carriers suitable for applications intended for increasing capacitation of mammalian sperm and treating infertility in mammalians including humans. One of skill in the art would have been motivated to adjust amounts and carriers for the expected benefits in maximizing effects related to sperm capacitation and mammalian infertility treatments.

Thus, the claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

With regard to WO 95/32725 applicant appears to argue that in the particular disclosure the cited document demonstrates the angiotensin II effects as related to sperm motility and that sperm capacitation is not the same as sperm motility. This is not found persuasive with respect to the instant claims because sperm capacitation is required for and directly relates to sperm fertilization capability and egg fertilization depends on and requires the sperm motility. Moreover, the cited document teaches the use of angiotensin II for promoting fertilization of mammalian eggs with sperm, and, therefore, the teaching of the cited patent clearly relates to the subject matter of the instant application and claims.

With regard to the reference by Suzuki et al. applicant appears to argue that the teaching of the cited reference confuses terms sperm "capacitation" and sperm "acrosome reaction" as related to the effects of calcitonin. This is not found persuasive because sperm capacitation and sperm acrosome reaction are related events in the light of the instant specification (page 1, line 9). The cited reference by Suzuki et al. on its face clearly states "calcitonin induced the capacitation" and the cited reference is relied thereupon.

With respect to the cited reference by Fraser the mere argument that at the time of the publication date of the cited article professor Fraser had not begun to study calcitonin effects on sperm capacitation in compositions with FPP and adenosine is not un indication or objective

evidence that it would not have been obvious to one having ordinary skill in the art at the time the claimed invention was made.

Applicant appears to argue that there is no suggestion to combine the cited references. However the references are in the same field of endeavor and seek to solve the same problems as the instant application and claims, and one of skill in the art is free to select components available in the prior art. In re Winslow, 151 USPQ 48 (CCPA, 1966).

The applicant' declaration filed 2/33/2004 and arguments based thereon have been fully considered however they are not persuasive because the results of the declaration are confusing as to the significance of the differences in material and functional characteristics and productivity indicated as related to the instant claims. The contents of the submitted declaration relates to the differences between calcitonin amounts in the calcitonin-containing compositions in the methods for sperm capacitation but the scope of the instants claims requires a combination of several agents in compositions with calcitonin. The scope of the showing must commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980).

It should be clear that the probative value of the data should commensurate in scope with the degree of protection sought by the claim. Therefore, with respect to the major component concentration as indicated in the narrowest claims 54-57, it is further noted that the calcitonin, angiotensin II, FPP and adenosine might be found in animal seminal plasma at least in some amounts (specification pages 1-3) and in, thus, they might be present in animal semen samples.

Thus, the evidence probative of unexpected results would need to demonstrate the differences in concentrations.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Vera Afremova

AU 1651

May 19, 2004

VERA AFREMOVA

PATENT EXAMINER